

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

jc586 U.S. PTO  
09/559344  
04/27/00

In re Application of: )

Claude NÉGRIER et al. )

Serial No.: Not Yet Assigned )

Group Art Unit: Not Yet Assigned

Filed: Concurrently Herewith )

Examiner: Not Yet Assigned

For: DNA CONSTRUCT FOR THE TISSUE )  
EXPRESSION OF A BLOOD )  
COAGULATION FACTOR )

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicants bring to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed within three months of the filing date of the above-referenced application.

Copies of the listed documents are attached and the United States counterpart, U.S. Patent No. 5,656,358 of the non-English document, WO 93/00438 is enclosed.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or

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constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

By: Carol P. Einaudi  
Carol P. Einaudi  
Reg. No. 32,220

Date: April 27, 2000

**INFORMATION DISCLOSURE CITATION**  
(Use several sheets if necessary)

6478.1442

Serial No.: Not Yet Assigned

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Group

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PTO  
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**U.S. PATENT DOCUMENTS**

Examiner Initial*	Document Number	Date	Name	Class	Sub Class	Filing Date If Appropriate
	5,565,358	10/15/96	Marguerie de Rotrou et al.	435	320.1	9/30/94

**FOREIGN PATENT DOCUMENTS**

Document Number	Date	Country	Class	Sub Class	Translation Yes or No
WO 93/00438	01/07/93				YES

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	UZAN, Georges et al., "Regulation of Gene Transcription During the Differentiation of Megakaryocytes", Thrombosis and Haemostasis, Vol. 74, pp. 210-212 (1995).
	KURACHI, Kotoku et al., "Regulatory Mechanism of the FxIII Gene", Thrombosis and Haemostasis, Vol. 73, pp. 333-339 (1995).
	SALIER, Jean-Philippe et al., "Functional Characterization of the 5'-Regulatory Region of Human Factor IX Gene", The Journal of Biological Chemistry, Vol. 265, No. 12, pp. 7062-7068 (April 25, 1990).
	CAMERINO, G. et al., "Regional Localization on the Human X Chromosome and Polymorphism of the Coagulation Factor IX Gene (Hemophilia B Locus)", Proc. Natl. Acad. Sci., Vol. 81, pp. 498-502 (Jan. 1984).
	YOSHITAKE, Shinji et al., "Nucleotide Sequence of the Gene for Human Factor IX (Antihemophilic Factor B)", Biochemistry, Vol. 24, pp. 3736-3750 (1985).
	BOYD, Y. et al., "Assignment of the Haemophilia B (Factor IX) Locus to the q26-qter Region of the X Chromosome", Ann. Hum. Genet., Vol. 48, pp. 145-152 (1984).
	ROBERTS, Harold R., "Molecular Biology of Hemophilia B", Thrombosis and Haemostasis, Vol. 70, pp. 1-9 (1993).
	NAKAI, Hiroyuki et al., "Adeno-Associated Viral Vector-Mediated Gene Transfer of Human Blood Coagulation Factor IX Into Mouse Liver", Blood, Vol. 91, No. 12, pp. 4600-4607 (June 15, 1998).
	WHITE, Steve J. et al., "Long-Term Expression of Human Clotting Factor IX From Retrovirally Transduced Primary Human Keratinocytes <i>In Vivo</i> ", Human Gene Therapy, Vol. 9, pp. 1187-1195 (May 20, 1998).
	BARU, Moshe et al., "Retroviral-Mediated <i>In Vivo</i> Gene Transfer into Muscle Cells and Synthesis of Human Factor IX in Mice", Intervirology, Vol. 38, pp. 356-360 (1995).
	WANG, Jian-Min et al., "Persistent Systemic Production of Human Factor IX in Mice by Skeletal Myoblast-Mediated Gene Transfer: Feasibility of Repeat Application to Obtain Therapeutic Levels", Blood, Vol. 90, No. 3, pp. 1075-1082 (August 1, 1997).
	CHERINGTON, Van et al., "Retroviral Vector-Modified Bone Marrow Stromal Cells Secrete Biologically Active Factor IX <i>In Vitro</i> and Transiently Deliver Therapeutic Levels of Human Factor IX to the Plasma of Dogs After Reinfusion", Human Gene Therapy, Vol. 9, pp. 1397-1407 (July 1, 1998).
	HAO, Qian-Lin et al., "Expression of Biologically Active Human Factor IX in Human Hematopoietic Cells After Retroviral Vector-Mediated Gene Transduction", Human Gene Therapy, Vol. 6, pp. 873-880 (July 1995).

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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**FOREIGN PATENT DOCUMENTS**

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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	MARTIN, Paul et al., "HEL Cells: A New Human Erythroleukemia Cell Line With Spontaneous and Induced Globin Expression", Science, Vol. 216, pp. 1233-1235 (June 1982).
	TABILIO, A. et al., "Expression of Platelet Membrane Glycoproteins and $\alpha$ -Granule Proteins by a Human Erythroleukemia Cell Line (HEL)". EMBO J, Vol. 3, pp. 453-459 (1984).
	LONG, Michael W. et al., "Regulation of Megakaryocyte Phenotype in Human Erythroleukemia Cells", Clinical Investigation, Vol. 85, pp. 1072-1084 (April 1990).
	NISHIZUKA, Yasutomi, "The Role of Protein Kinase C in Cell Surface Signal Transduction and Tumour Promotion", Nature, Vol. 308, pp. 693-698 (April 19, 1984).
	HONG, Ying et al., "Inhibition of Protein Kinase C Suppresses Megakaryocytic Differentiation and Stimulates Erythroid Differentiation in HEL Cells", Blood, Vol. 87, No. 1, pp. 123-131 (January 1, 1996).
	HAAS, Thomas A. et al., "Integrin-Ligand Interactions: A Year in Review", Current Opinion in Cell Biology, Vol. 6, pp. 656-662 (1994).
	UZAN, Georges et al., "cDNA Clones for Human Platelet GPIIb Corresponding to mRNA From Megakaryocytes and HEL Cells", Eur. J. Biochem., Vol. 171, pp. 87-93 (1988).
	FRACHET, Philippe et al., "GPIIb and GPIIIa Amino Acid Sequences Deduced From Human Megakaryocyte cDNAs", Molecular Biology Reports, Vol. 14, pp. 27-33 (1990).
	PRANDINI, M.H. et al., "Isolation of the Human Platelet Glycoprotein IIb Gene And Characterization of the 5' Flanking Region", Biochemical and Biophysical Research Communications", Vol. 156, No. 1, pp. 595-601 (Oct. 14, 1988)
	BRAY, Paul F. et al., "Platelet Glycoprotein IIb", J. Clin. Invest., Vol. 80, pp. 1812-1817 (Dec. 1987).
	UZAN, Georges et al., "Tissue-Specific Expression of the Platelet GPIIb Gene", The Journal of Biological Chemistry, Vol. 266, No. 14, pp. 8932-8939 (May 15, 1991).

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